DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region

D1250B

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (201) 331-2910

March 11, 1997

WARNING LETTER

RELEASE

REVIEWED BY MK 3/13/97
C.O. DATE

CERTIFIED MAIL-
RETURN RECEIPT REQUESTED
Ervin Schoenblum, Acting President
ELectro Catheter Corp.
2100 Felver Court
Rahway, New Jersey 07065

File No: 97-NWJ-22

Dear Mr. Schoenblum:

During an inspection of your firm located at 2100 Felver Ct., Rahway, New Jersey, and 10 G&H Englehard Ave., Avenel, New Jersey, between February 6 and 21, 1997, our investigators determined that your firm manufactures cardiac catheters, labeled as "sterile," for pacing, monitoring and electrophysiology. Cardiac catheters are medical devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these cardiac catheters are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with Good Manufacturing Practice (GMP) for Medical Device Regulations, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Your firm's investigation of confirmed device failures, lacked documentation to show the cause regarding why the complaints occurred. For example,

   A. Complaint #60912-1, dated 9/12/96, (Balectrode); complaint #60912-2, dated 9/12/96, (Pacewedge); and complaint #6-0102-1, dated 1/02/96, (Pacewedge); all reported balloon problems. However, there is no documentation of an investigation into why these complaints occurred.

   B. Complaint #6-0822-1, dated 8/22/96, and complaint #6-819-2, dated 8/19/96, both reported a cracked tip on the Balectrode balloon catheter. However, there is no documentation of an investigation into why these complaints occurred.

2. Your validation of the sterilization cycle for devices sterilized by EtO, dated June 23, 1994, is inadequate due to the following:

   A. Your half cycle and full cycle sterilization validation was conducted using mixed loads of product. There is no data to show equivalency of the products or product families in the mixed loads, regarding size, density, etc.

      Also, it is unclear from the data presented if 12 or 16 boxes of product, on six pallets, was used during the validation.

   B. There is no explanation of how the configuration of mixed loads for sterilization lot numbers GH105, GH106, and GI119, was determined nor what constitutes "dunnage."

   C. Your Cloverleaf Pacing Probe, Open Tip Catheter and Ventricular Pacing Pressure Thermal Dilution Catheter can be resterilized with EtO. However, there is no data to show that resterilization does not adversely affect the product, its packaging, and that product can meet ethylene oxide residuals.

   D. Your firm did not use product sterility samples as stated in your validation protocol, dated June 23, 1994.

3. There is no assurance that changes to devices manufactured by Electro Catheter Corp., are validated. For example,

   A. Interim specification #0235, dated 10/17/96, with an expiration date of 4/17/97, shows dimensional changes to the threads on the handle of the Tip Deflector Catheter. On 2/07/97, a new specification was approved with new dimensions. Neither specification change contained documentation to indicate that the form, fit, nor function of the device was not adversely affected after the change.

B. ECN #2276, dated 5/29/96, states that there were dimensional changes to the single lumen vinyl tubing, (VLY-10), as well as, a die and tip change. There is no documentation to demonstrate that the tubing changes will not have an adverse affect on the finished device.

4. Your extrusion process does not provide assurance that acceptable tubing would be consistently manufactured, since your validation completed in 1995, lacked the following:

A. A quantifiable functional test of the tubing after extrusion, such as tensile and elongation.

B. Validation trial runs at the high and low end of your specification. For instance,

i) The specifications for Pebax-60 includes a screw speed of [redacted] However, product run during the validation was conducted at [redacted] rpm and not at the high end of the range, i.e [redacted] rpm.

ii) The specifications for VLY-66 include Zone #1 [redacted], Zone #2 [redacted] Zone #3 [redacted] and Zone #4 [redacted] The temperature range [redacted]. However, product run during the validation was conducted at [redacted] and not at the low end of the range, i.e. [redacted].

5. Your firm failed to qualify the [redacted] #1, which is used as the primary sterilization barrier packaging machine, and failed to qualify the [redacted] sealer, [redacted]

6. Your device master record (DMR) for the Tip Deflecting Probe-104 series, Balectrode 11KBE1, and Balectrode 11KBE2, lacks product/process specifications for individual devices; quality assurance procedures, including incoming and finished device test procedures; packaging and labeling specifications.

7. There is no assurance that the levels of bioburden on your product will meet specification. For example:

A. Quality Assurance Procedure 015, dated 6/21/94, requires products to be tested for bioburden every [redacted] months. Your firm did not adhere to this schedule as evidenced by bioburden testing being only conducted in May 1995; January, June, October and December of 1996.

B. According to QAP-015, dated 6/21/94, your alert level for the overall mean is [redacted] cfu/sample and [redacted] cfu per individual sample. The bioburden mean result for June 1996 was 772 cfu/sample and 1420 cfu, 1360 cfu, and 1500 cfu for individual samples.

C. Your firm failed to conduct environmental monitoring for 1996.

8. Samples taken 10/07/96 and recorded on the batch record for catheters 11KBE-2, lot #6073103 and lot #6080608, noted a sample level of S-2 and an AQL of 2.5. According to your Quality Assurance Procedure 008, dated 4/16/93, sampling is based upon [redacted] Level [redacted] with an AQL of [redacted]

Furthermore, it was noted that your firm may resterilize product via EtO. Please be advised that resterilized product must meet EtO residual specifications, as well as, product and package functionality.

The agency is in receipt of your written response, dated March 3, 1997, to the FDA 483 issued to your firm on February 21, 1997. Your response appears adequate, however, we believe that your target dates for completion of some of the above corrections are not timely. For example, you noted that your firm would complete tensile and elongation testing of tubing and would qualify your [redacted] heat sealers by August 15, 1997. This target date seems a little lengthy. Also, according to your response, bioburden and environmental corrections are not scheduled to be completed until February 1998. Again, NWJ-DO believes that this amount of time to correct the observations is not timely.

We acknowledge your firm's commitment to medical device cGMP's and the upcoming Quality System Regulation.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be system problems you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attention: Vincent P. Radice, Compliance Officer.

Very truly yours,

Paul D'Eramo
Acting District Director
New Jersey District Office

VPR:slw